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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:	Duncan W. MCBRANCH, et al.	ART UNIT:	1634
SERIAL NO.:	09/934,680	EXAMINER:	Frank Wei Min Lu
FILING DATE:	August 23, 2001		
FOR:	PEPTIDE NUCLEIC ACID BASED MOLECULAR SENSORS FOR NUCLEIC ACIDS		

PRE-APPEAL BRIEF REQUEST FOR REVIEW

ASSISTANT COMMISSIONER FOR PATENTS
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SIR:

Pursuant to the pilot program described at 1296 Off. Gaz. 67 (July 12, 2005, as extended on January 11, 2006), the Applicants hereby request pre-appeal brief review of the following rejections in this application:

Rejection of claims 1, 3-9, 12-13 and 24-25 under 35 U.S.C. § 103 over the combination of Heller (U.S. Patent No. 5,849,489) and Coull (U.S. Patent No. 6,355,421);

Rejections of dependent claims 10, 11 and 22 under 35 U.S.C. § 103 over Heller and Coull further in view of Chen (PNAS, 96, 12287-92, October, 1999), Woodrum (U.S. Patent No. 4,959,305), and Chick (U.S. Patent No. 5,342,789) respectively; and

Rejection for obviousness-type double-patenting of claims 1, 3-6, 8-13 and 26 over claims 1-18 of Whitten (U.S. Patent No. 6,743,640).

The present request is believed to be proper. The claims have been twice rejected, and a Notice of Appeal is submitted herewith.

An amendment is submitted herewith, which merely cancels dependent claim 6 and corrects the dependency of claim 7. The amendment should be entered, and its entry would not violate the pilot program requirements. This application is not under final, and the amendment is not a proposed amendment. Upon entry of the amendment, claims 1, 3-5, 7-13, 22 and 25-26 remain under consideration; claims 14-21 stand withdrawn; and claims 2, 6, 23 and 24 are canceled.

The Obviousness Rejections over Heller and Coull Should be Withdrawn for Clear Error

The present claims are drawn to a chemical moiety, which requires (1) a peptide nucleic acid sequence tethered to: (2) a fluorescent moiety; and (3) a property altering element. The general structure of the claimed chemical moiety has the order: fluorescent moiety – peptide nucleic acid sequence – property altering element. The peptide nucleic acid sequence acts as a recognition element that can bind to a target nucleic acid. When the peptide nucleic acid binds to a target nucleic acid, the fluorescence emitted from the fluorescent moiety is altered from that emitted when no binding occurs (Claim 1).

The Examiner, in rejecting the claims for obviousness, relies on: (1) Heller to provide the general structure of fluorescent moiety – DNA recognition element – property altering element; and (2) Coull to provide the peptide nucleic acid. The Examiner acknowledges that Heller is silent on peptide nucleic acids and that Coull is silent on the general structure. The Examiner asserts that it would be obvious to replace Heller's DNA recognition element with Coull's peptide nucleic acid. In so doing, the Examiner commits clear error, for he ignores Coull's teachings to the contrary.

Coull does not provide any motivation to substitute Heller's DNA with peptide nucleic acids. Coull does not disclose or suggest that peptide nucleic acids are equivalent to other types

of nucleic acids or could be substituted therefor. As seen below, Coull highlights the differences, and not the similarities, between peptide nucleic acids and other nucleic acids such as taught by Heller:

> "Despite the ability to hybridize to nucleic acid in a sequence specific manner, there are ***many differences*** between PNA [peptide nucleic acid] probes and standard nucleic acid probes. These differences can be conveniently broken down into biological, structural, and physico-chemical differences. As discussed in more detail below, these biological, structural, and physico-chemical differences ***may lead to unpredictable results*** when attempting to use PNA probes in applications where nucleic acids have typically been employed. This ***non-equivalency*** of differing compositions is often observed in the chemical arts."[1] (Emphasis added).
>
> "Structurally, PNA also differs ***dramatically*** from nucleic acid."[2] (Emphasis added).
>
> "The physico/chemical differences between PNA and DNA or RNA are also ***substantial***."[3] (Emphasis added).

One reviewing Coull would not conclude that Heller's nucleic acids could be easily or reliably substituted by Coull's peptide nucleic acids. Coull teaches that such a substitution would be at best unpredictable. See the Applicant's Response dated August 23, 2005, page 8.

The Examiner also ignores Heller's teachings why one need not use anything other than RNA or DNA. See the Applicant's Response, page 7.

The contrary teachings of Heller and Coull evidence the lack of motivation and expectation of success required to sustain the obviousness rejection. Maintaining the rejection is clear error. The rejection should be withdrawn accordingly.

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[1] Coull column 6, lines 1-13.

[2] Coull column 6, lines 25-26.

[3] Coull column 6, lines 52-53.

The Obviousness Rejections over Heller and Coull Further Combined with Chen, Woodrum, or Chick Should be Withdrawn for Clear Error

Neither Chen, Woodrum, nor Chick cure the contrary teachings of Heller and Coull with respect to the broadest claim, Claim 1. As such, they are not sufficient to sustain a rejection of the claims that depend from Claim 1. These rejections should be withdrawn.

The Double Patenting Rejection over Whitten Should be Withdrawn for Clear Error

The rejected claims are all drawn to a chemical moiety, in which the fluorescent moiety, peptide nucleic acid sequence recognition element, and property altering element are tethered together, in a particular order.

In contrast, Whitten claims 1-18 are drawn to: (1) a composition, in which the fluorescent moiety is either not tethered or is tethered in a different order from what is presently claimed; (2) a kit, in which the fluorescent moiety is not tethered or is completely separated; and (3) a method of using the Whitten composition. The Applicants fail to see how the present claims, drawn to a chemical moiety with parts tethered together in a particular order, can obviously overlap with the Whitten claims, drawn as they are to a composition, a kit, and a method. The double-patenting rejection should be withdrawn.

Conclusion

For all the reasons above, the rejections should be withdrawn for clear error, and this application should be passed to allowance. An early indication of same is kindly requested.

Respectfully submitted,

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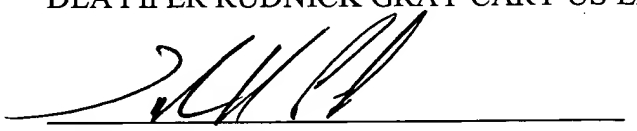

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